

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING )  
PHARMACY, INC., PRODUCTS LIABILITY )  
LITIGATION )  
 ) MDL No.: 2419  
 ) Master Docket No.: 1:13-md-2419-FDS  
\_\_\_\_\_)  
THIS DOCUMENT RELATES TO: )  
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\_\_\_\_\_)  
All Actions Against St. Thomas Neurosurgical)

**PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM IN SUPPORT OF  
MOTION TO COMPEL COMPLIANCE WITH SUBPOENA TO MICHAEL O'NEAL**

On August 19, 2015, the PSC issued a subpoena to Michael O'Neal, seeking both documents and testimony.<sup>1</sup> Mr. O'Neal refuses to comply with the subpoena, contending that the Tennessee Peer Review Privilege and the Tennessee Quality Improvement Committee Privilege shield him from testifying and providing responsive records. Because neither privilege applies, the PSC moves to compel Mr. O'Neal to testify, to produce relevant non-privileged records, and to produce a privilege log for any materials withheld.

**LOCAL RULE 37.1 CONFERENCE**

The current motion to compel relates to a subpoena issued to Michael O'Neal on August 19, 2015. On August 28, 2015, Benjamin A. Gastel, appearing on behalf of the PSC, and Steve Elliott, appearing on behalf of Mr. O'Neal, held a Rule 37.1 conference to discuss that subpoena. On that day, counsel for Mr. O'Neal indicated that he believed the vast majority of the information sought by the subpoena would be covered by privilege and he indicated that a motion to quash the subpoena would be forthcoming.

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<sup>1</sup> Declaration of Benjamin A. Gastel in Support of Motion to Compel ("Gastel Decl."), Exhibit ("Ex.") 1.

Having never received the motion to quash and in anticipation of filing the present motion, Mr. Gastel held another Rule 37.1 conference on November 19, 2015 to discuss the subpoena with counsel for Mr. O'Neal, this time with Mr. Thomas Pinckney appearing on behalf of the witness. Both parties agreed that to conduct an appropriate deposition of Mr. O'Neal the parties would need guidance from the Court on the scope of applicable privilege and what, if any, information could be solicited in deposition and which documents should be produced in accordance with the subpoena.

### **BACKGROUND**

The PSC's subpoena to Mr. O'Neal seeks information relevant to the fungal meningitis cases involving defendant St. Thomas Outpatient Neurological Center ("St. Thomas Neurosurgical"), a clinic located on the St. Thomas Hospital campus in Nashville, Tennessee.

#### **I. St. Thomas Neurosurgical's Decision to Purchase MPA from NECC in June 2011**

Discovery in the MDL indicates that St. Thomas Neurosurgical began to purchase compounded MPA from the New England Compounding Center ("NECC") in June 2012.<sup>2</sup> At deposition, Facility Director Debra Schamberg, R.N. testified that she and John Culclasure, M.D., were the only individuals at St. Thomas Neurosurgical who were involved in the company's decision to purchase compounded products (including MPA) from NECC.<sup>3</sup> At deposition, Ms. Schamberg stated that, other than having a handful of conversations with Dr. Culclasure and taking NECC's promotional materials at face value, she did not conduct any diligence before deciding to purchase MPA from NECC.<sup>4</sup>

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<sup>2</sup> Gastel Decl., Ex. 2, Transcript of Deposition of Debra Schamberg, R.N. ("Schamberg Tr."), at 66:15-22.

<sup>3</sup> Schamberg Tr. at 55:25-56:10.

<sup>4</sup> Schamberg Tr. at 77:5-78:13-23 and 82:17-83:7.

## **II. St. Thomas Neurosurgical's Retention of Michael O'Neal**

According to Ms. Schamberg, St. Thomas Neurosurgical does not have an in-house pharmacist; instead, it contracted with Michael O'Neal, a licensed Tennessee pharmacist, to provide pharmacy expertise.<sup>5</sup>

### **A. Records Related to O'Neal's Retention**

As explained in the Gastel Declaration, St. Thomas Neurosurgical participated in discovery in Tennessee Circuit Court in *Wayne Reed v. St. Thomas Neurosurgical, et al.*, No. 13C417, a case that was ultimately voluntarily dismissed, refiled in federal court, and consolidated into MDL 2419. In the course of proceedings before the state court, the parties disputed whether information concerning O'Neal was privileged and discoverable, and the plaintiff filed a Motion to Compel on April 30, 2013. In the course of that dispute, St. Thomas Neurosurgical filed, *inter alia*, (1) the Affidavit of Michael O'Neal (Gastel Decl., Ex. 3 ("O'Neal Affidavit")), which attached copies of two contracts with St. Thomas Neurosurgical, (2) a redacted version of the second contract (Gastel Decl., Ex. 4); (3) an Affidavit from Debra Schamberg (Gastel Decl., Ex. 5 ("Schamberg Affidavit")); and (4) unredacted versions of both contracts (Gastel Decl., Ex. 6). The first contract, entitled "Pharmacy Consulting Contract," purports to have become effective February 2007 (the "2007 O'Neal Contract"). The second contract purports to have become effective in September 2012 (the "Second O'Neal Contract"). Correcting for some pagination errors in the state court filings and for clarity of the record, the PSC has attached the 2007 O'Neal Contract and the Second O'Neal Contract as Exhibits 7 and 8 to the Gastel Declaration, respectively.<sup>6</sup>

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<sup>5</sup> Schamberg Tr. at 279:10-21.

<sup>6</sup> As explained in the Schamberg and O'Neal Affidavits, the contracts contain some discrepancies regarding the names of the contracting entities, but both aver that the contracts

**B. The 2007 O’Neal Contract and the Second O’Neal Contract: Material Differences, Discrepancies, and Questionable Timing**

Effective February 2007, St. Thomas Neurosurgical and O’Neal entered into the 2007 O’Neal Contract.<sup>7</sup> The contract, which is a single page document, states that O’Neal was hired to perform specific duties, such as “consultation to [sic] all laws, rules, and regulations and the administration of such at the Surgery Center,” “[a]ssist the center in maintaining its accreditation status by all of its governing bodies,” “[d]evelop and aid in maintaining policies and procedures pertaining to any medication bought or administered,” to “[t]each staff to check stock medications for outdated medications before they are administered,” and “to establish record-keeping procedures, forms and documents necessary to meet existing accreditation body, state and federal regulations concerning such.” The 2007 O’Neal Contract makes no reference to a “peer review committee,” “medical review committee,” or any other “committee” of St. Thomas Neurosurgical, nor does it state that Mr. O’Neal was engaged by (or would be performing work for) any St. Thomas Neurosurgical committee.

St. Thomas Neurosurgical began purchasing MPA from NECC in June 2011, and St. Thomas Neurosurgical administered contaminated MPA to its patients through September 2012 – all within the time frame covered by the 2007 O’Neal Contract.

At some point in or after September 2012, O’Neal and St. Thomas Neurosurgical entered into the Second O’Neal Contract.<sup>8</sup> Before discussing the substance of that agreement, the PSC directs the Court to examine the last page of the contract and “Exhibit A” to the contract. For reasons that will not be clear unless the PSC has the opportunity to question Mr. O’Neal, Mr.

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were in fact between St. Thomas Neurosurgical and O’Neal. For purposes of this motion, the PSC assumes that fact to be true.

<sup>7</sup> Gastel Decl., Ex. 8.

<sup>8</sup> Gastel Decl., Ex. 9.

O’Neal executed the agreement and Exhibit A thereto *on April 4, 2013* – not in September 2012. Nevertheless, the agreement purports to be effective *as of September 1, 2012*.<sup>9</sup> It is also suspicious that O’Neal signed the document in the midst of a discovery dispute, and just weeks before the plaintiff his Motion to Compel. The Court should therefore assume that the Second O’Neal Contract was not effective until April 2013.

Leaving aside that provocative issue, the terms of the Second O’Neal Contract are materially different than the terms of the 2007 O’Neal Contract. In addition to some of the duties set forth in the 2007 O’Neal Contract, the Second O’Neal Contract states that O’Neal was to “[a]ssist in the development for [sic] Quality Improvement Process regarding medication management related procedures and attends and participates [sic] in the quarterly Quality Improvement Process meetings when applicable and available.”<sup>10</sup> The Second O’Neal Contract, which went into effect in September 2012 at the earliest (and likely not until April 2013), represents the first instance in which O’Neal explicitly contracted to perform “Quality Improvement Process” services for St. Thomas Neurosurgical.

### **C. The O’Neal and Schamberg Affidavits: Characterization Over Substance**

In the O’Neal Affidavit, O’Neal avers that he performed monthly inspections at St. Thomas Neurosurgical from 2007 forward.<sup>11</sup> Leaving aside his attempts to characterize the nature of his activities, he avers that: he “ensures” (present tense) that St. Thomas Neurosurgical staff members are properly carrying out internal checks concerning their medications; he evaluates and reviews the “method, procedures, and/or treatments” at St. Thomas Neurosurgical

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<sup>9</sup> At her deposition, Ms. Schamberg refused to answer questions concerning St. Thomas Neurosurgical’s relationship to Mr. O’Neal, claiming privilege at the suggestion of her counsel. Schamberg Tr. at 277:16-279:9. The PSC has not yet challenged Ms. Schamberg’s invocation of the privilege, but reserves the right to do so.

<sup>10</sup> Second O’Neal Contract at ¶ 2.J.

<sup>11</sup> O’Neal Affidavit, ¶ 13.

“with respect to medications,” he “create[s] reports identifying areas of excellence and those in need of improvement,” which he forwards to (and sometimes discusses with) Ms. Schamberg and another individual, Cindy McClendon; and, notwithstanding the material differences between the 2007 O’Neal Contract and the Second O’Neal Contract, his duties for St. Thomas Neurosurgical have always been the same.<sup>12</sup>

Schamberg avers that O’Neal ensures that St. Thomas Neurosurgical is operating in compliance with applicable state and federal laws regarding medications, properly carries out “internal checks regarding its medications,” and reviews St. Thomas Neurosurgical’s activities relating to the purchase, use, and storage of medications.<sup>13</sup> Schamberg also avers that O’Neal “creates reports identifying areas of excellence and those in need of improvement,” which O’Neal discusses with Schamberg.<sup>14</sup> Without providing dates as to when the committee came into being, Schamberg avers that, “[a]s a member of [St. Thomas Neurosurgical’s] Medical Executive Committee, I relay the substance of those reports to the remaining committee members, and we discuss his evaluations and recommendations.”<sup>15</sup>

A careful reading of the balance of the O’Neal and Schamberg Affidavits reflects that both affidavits are heavy on characterization and light on substance, and that both affidavits raise more questions than answers. Neither affidavit addresses the differences between the two contracts, the date discrepancies in the Second O’Neal Contract, why St. Thomas Neurosurgical entered into a new contract with O’Neal during the fungal meningitis outbreak, why O’Neal apparently signed the document in the midst of a discovery dispute, when a “Medical Review Committee” came into being (in 2007? in 2013?), the precise nature of O’Neal’s activities and

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<sup>12</sup> See O’Neal Affidavit, ¶¶ 13-19.

<sup>13</sup> Schamberg Aff., ¶¶ 14, 15, and 17.

<sup>14</sup> Schamberg Aff., ¶¶ 18-20.

<sup>15</sup> Schamberg Aff. ¶¶ 19.

their relationship to this purported Medical Review Committee, and whether and when a Medical Review Committee utilized O’Neal’s reports in evaluating the conduct of other physicians. Most of the averments in both affidavits are in the present tense, making it impossible to determine the time frame covered by each statement – a crucial detail for the reasons explained herein.

Moreover, because O’Neal and Schamberg have a strong incentive to shield themselves from disclosure, there is no reason for the court to assume that their self-serving characterizations of O’Neal’s duties are true, particularly where some of the averments (such as Schamberg’s contention that O’Neal’s duties never changed) are inconsistent with the contractual terms.

Again, it is suspicious that O’Neal executed a contract in *April 2013* – approximately six months after the outbreak – by adding a contractual reference that conveniently attempts to track the requirements of Tennessee’s Quality Improvement Committee Privilege statute.

#### **D. PSC Subpoena**

On August 19, 2015, the PSC issued a Rule 45 subpoena to Mr. O’Neal for both records and testimony. Mr. O’Neal contends that most, if not all, of the information in his possession is privileged from disclosure. Mr. O’Neal has indicated that he would produce only his billing records, while withholding all other information. He has also indicated that, while he would sit for deposition, he would claim privilege in response to practically any substantive question posed by the PSC. The PSC and Mr. O’Neal are at an impasse concerning the scope of questioning and records that Mr. O’Neal must produce. The parties agree that they require a ruling from the Court on the scope of Mr. O’Neal’s right to claim privilege under Tennessee’s Peer Review Privilege or Quality Improvement Committee Privilege.

#### **TENNESSEE PRIVILEGE LAW: TWO DISTINCT REGIMES**

##### **I. The PRP (applicable through April 12, 2011) and the QCIP (only Applicable for April 12, 2011 Forward)**

Mr. O’Neal’s claim of absolute privilege relates to two Tennessee statutory privileges – not just one.<sup>16</sup> The first is the “Peer Review Privilege,” which was in effect (in one form or another) from **1967 through April 12, 2011** (the “PRP”).<sup>17</sup> The second is the Quality Improvement Committee Privilege (the “QICP”), which was in effect from **April 12, 2011 forward**, and which the PSC concedes has a wider scope than the PRP.<sup>18</sup>

In analyzing Mr. O’Neal’s claim of privilege, the Court should be careful to distinguish (1) between the PRP and the QICP, and (2) whether Mr. O’Neal was operating under the 2007 O’Neal Contract or the Second O’Neal Contract. The PRP and QICP are *not the same*, and the QICP did not become effective until *April 12, 2011*; similarly, the terms of the 2007 O’Neal Contract and Second O’Neal Contract are *not the same*. As explained herein, the Court in fact faces as many as three distinct analyses as to the circumstances under which O’Neal can claim privilege:

- **For activities and records from 2007 through April 12, 2011**, whether he can claim privilege **under the PRP**.
- For activities and records from **April 12, 2011** forward, whether he can claim can privilege **under the QCIP** for (a) the time frame from April 12, 2011 through the operative date of the Second O’Neal Contract, and (b)

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<sup>16</sup> Under Fed. R. Civ. P. 501, state law governs the privileges available to Mr. O’Neal. For purposes of this motion only, the PSC will assume that Tennessee substantive law governs application of the privilege to Mr. O’Neal, a third party to this litigation. However, the PSC has argued to the Court that Massachusetts law should govern lawsuits involving the Tennessee Clinic Defendants. Should the Court rule in the PSC’s favor on that motion, the PSC reserves the right to argue that Massachusetts law governs Mr. O’Neal’s claim of privilege and that Massachusetts law does not entitle Mr. O’Neal to claim privilege in response to the subpoena.

<sup>17</sup> See Tenn. Code Ann. § 63-6-219 (repealed). To assist the court, the version of the law in effect from 2010 through its date of repeal is attached as Exhibit 10 to the Gastel Declaration.

<sup>18</sup> The QICP is codified in two sections of the Tennessee Code: Tenn. Code Ann. § 68-11-272 and Tenn. Code Ann. § 63-1-150. Aside from a small difference in the numbering of subsections, both statutes are essentially identical. For ease of reference and consistent with the parties’ citations in the state court action, the PSC will refer only to subsections within Tenn. Code Ann. § 68-11-272 in this brief.



the time frame from the operative date of the Second O’Neal Contract forward.

Thus, the Court should be wary of any effort by O’Neal to have the Court conflate these crucial distinctions in its analysis.<sup>19</sup>

## **II. Tennessee Privilege Considerations**

In determining whether the PRP or the QCIP applies, the Tennessee Supreme Court has indicated that the Court’s judgment should be guided by three principles: (1) Tennessee’s discovery rules favor discovery of all relevant, non-privileged information; (2) even though privileges do not facilitate the fact-finding process, they are designed to protect interests and relationships that are regarded as sufficiently important to justify limitations on discovery; and (3) while statutory privileges should be fairly construed according to their plain meaning, *they should not be broadly construed*.<sup>20</sup>

## **TENNESSEE PEER REVIEW PRIVILEGES AND THEIR APPLICATION**

### **I. The Peer Review Privilege (Applicable Through April 12, 2011)**

#### **A. Tennessee Peer Review Privilege**

In determining whether the PRP applies, the court must determine (1) whether the subject matter of the underlying proceeding is within the subject matter covered by the statute, and (2) whether the person or entity from whom the information is sought is a person or entity covered by the statute.<sup>21</sup> If the answer to either question is “no,” then the information sought is *not* privileged and the Court should permit discovery of that information. If the answer to both

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<sup>19</sup> As described herein, that was the successful strategy employed by St. Thomas Neurosurgical before the Tennessee Circuit Court, which thereby generated a clearly erroneous ruling from the Circuit Court on a similar issue.

<sup>20</sup> *Lee Med, Inc. v. Beecher*, 312 S.W.3d 515, 525-26 (Tenn. 2010); *Powell v. Cmty. Health Sys.*, 312 S.W.3d 496, 504 (Tenn. 2010). *Lee* and *Powell* were companion decisions issued on the same day.

<sup>21</sup> *Powell*, 312 S.W.3d at 504; *Lee*, 312 S.W.3d at 529-30.

questions is “yes,” then the Court must proceed to address other specific disputes regarding the invocation of the privilege that may have been raised.<sup>22</sup>

Although O’Neal (and parties to the fungal meningitis cases) have invoked the PRP as a blanket privilege for any communications involving O’Neal, the Tennessee Supreme Court has made clear that the PRP is a *limited privilege* that applies only in *specific narrow circumstances*. As explained in *Lee*, the PRP “applies only to **peer review proceedings** before a **peer review committee** as defined in Tenn. Code Ann. § 63-6-219(c) that involve **a physician’s conduct, competence, or ability to practice medicine.**”<sup>23</sup>

In other words, the PRP applies only to physicians and, as a consequence, it is not generally applicable to other health care professionals or entities.<sup>24</sup> Thus, “[i]t does not apply to records kept by a hospital in the regular course of its business unrelated to a peer review committee conducting a proceeding involving a physician’s professional conduct, competence, or ability to practice medicine.”<sup>25</sup> Similarly, “it does not apply to records in the custody of original sources who did not prepare the record for use by a peer review committee in a peer review proceeding.”<sup>26</sup> A “peer review proceeding is a proceeding involving a physician’s professional conduct, competence, or ability to practice medicine.”<sup>27</sup> The Tennessee Supreme Court has held that limiting the PRP to peer review proceedings involving a physician’s professional conduct, competence, or ability to practice medicine “provides *a bright line of demarcation* between records relating to peer review proceedings involving physicians that are

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<sup>22</sup> *Powell*, 312 S.W.3d at 504.

<sup>23</sup> *Lee*, 312 S.W.3d at 526.

<sup>24</sup> *Lee*, 312 S.W.3d at 532.

<sup>25</sup> *Lee*, 312 S.W.3d at 536.

<sup>26</sup> *Lee*, 312 S.W.3d at 536.

<sup>27</sup> *Lee*, 312 S.W.3d at 536.

privileged and other records made in the regular course of the hospital's business that are not privileged under [the PRP]."<sup>28</sup>

With respect to third parties, the PRP applies to information that was created at the behest of a peer review committee, including information gathered or prepared by the members of the committee and information gathered or prepared by others at the committee's request.<sup>29</sup>

However, just as with deliberations of a peer review committee itself, the PRP only applies to third parties if the information is "used for peer review purposes;" thus, "[i]f it originated outside the peer review process, it is not privileged."<sup>30</sup>

In applying these limitations on the privilege, the Tennessee Supreme Court has emphasized that the PRP does not provide a blanket privilege for all activities of, or communications with, a peer review committee. For example, in *Lee*, the plaintiff sued the defendants (a hospital network) for their decision to provide vascular access services in-house rather than to continue to outsource them through the plaintiff.<sup>31</sup> In the course of making that decision, multiple committees within the hospital network had reviewed and evaluated a report concerning the plaintiff's performance of vascular access services and the financial consequences of moving the business in house.<sup>32</sup> The defendants claimed privilege over the report and the associated deliberations concerning it, but the Tennessee Supreme Court found that the PRP did not apply. Although the court found that certain committees of the defendants did constitute "peer review committees" under § 219(c), it held that the PRP did not apply because those committees' deliberations concerning the provision of vascular access services

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<sup>28</sup> *Lee*, 312 S.W.3d at 536 (emphasis added).

<sup>29</sup> *Powell*, 312 S.W.3d at 509.

<sup>30</sup> *Powell*, 312 S.W.3d at 509.

<sup>31</sup> *Lee*, 312 S.W.3d at 519-20.

<sup>32</sup> *Lee*, 312 S.W.3d at 519-20.

“did not involve the professional conduct, competence, or ability to practice medicine of any physician.”<sup>33</sup>

**B. The PRP – not the QCIP – Governs O’Neal’s Claim of Privilege for Pre-April 12, 2011 Activities**

Here, the 2007 O’Neal Contract was in force through April 12, 2011, when Tennessee repealed the PRP statute in favor of a new law. Thus, for all activities through April 12, 2011, the PRP determines whether O’Neal may claim a privilege from disclosure.

The PSC anticipates that O’Neal will argue that the QCIP statute, which became effective in April 12, 2011, applies retroactively. Although the PSC has not located any Tennessee authority concerning retroactivity of the QCIP statute, other state courts analyzing hospital peer review laws and other privilege laws have found that the laws do *not* apply retroactively, absent an explicit statement to that effect by the legislature. For example, in *Davison v. St. Paul Fire & Marine Ins. Co.*, 248 N.W. 2d 433 (Wis. 1997), a hospital contended that an intervening amendment to the Wisconsin peer review committee privilege statute applied retroactively to shield from disclosure any proceedings that occurred prior to the amendment. In evaluating whether to apply the statute retroactively, the Supreme Court of Wisconsin observed that the hospital did not hold a statutory right of privilege at the time that it created the records at issue, that the plaintiffs were unable to obtain the records by other means, that non-disclosure impacted the plaintiffs’ substantive rights, and that the legislature could have (but did not) state that the law was to apply retroactively.<sup>34</sup> The court therefore found that the newer version of the law did not apply retroactively and that the hospital did not have a statutory privilege against disclosure

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<sup>33</sup> *Lee*, 312 S.W.3d at 537.

<sup>34</sup> *Davison*, 248 N.W.2d at 439.

of those records.<sup>35</sup> Other courts considering amendments to peer review privilege statutes similarly have refused to apply those laws retroactively, absent a statement of legislative intent.<sup>36</sup>

The same principles that animate the decisions in those cases apply here and indicate that the Court should evaluate O’Neal’s claim of privilege as to pre-April 12, 2011 materials under the PRP. Where the QCIP did not apply to O’Neal activities before April 12, 2011, O’Neal cannot have communicated with St. Thomas Neurosurgical before April 12, 2011 with the reasonable expectation that the communications would be privileged under that statute. Furthermore, the Tennessee General Assembly repealed the PRP statute and enacted a new statute, the QICP law. The Tennessee General Assembly could have, but did not, state that the new law would apply retroactively. In Tennessee (as with other states), “in the absence of legislative intent or a necessary inference that a statute is to have retroactive force, an act of the legislature is to be given prospective effect only by the courts.”<sup>37</sup> Indeed, the Tennessee Supreme Court has held that courts must apply a statute prospectively, unless there is “the most clear and unequivocal expression to the contrary” and, “in every case of doubt, the doubt must be

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<sup>35</sup> *Davison*, 248 N.W.2d at 439.

<sup>36</sup> *See, e.g., Venosh v. HENZES*, No. 11 CV 3058. 2013 Pa. Dist. & Cnty. Dec. LEXIS 390, at 15-16 (Pa. Ct. of Common Pleas July 17, 2013), *aff’d* 2014 Pa. Super. Unpub. LEXIS 2906 (July 11, 2014) (holding that amended Pennsylvania peer review privilege statute did not apply retroactively to records created while earlier version of law was in effect, because records could not have been prepared with the expectation that they would be privileged); *Matviuw v. Johnson*, 444 N.E.2d 606, 609 (Ill. Ct. App. 1982) (finding that trial court properly refused to apply amended version of Illinois peer review privilege statute retroactively, where statute was enacted to change the law rather than simply to clarify an existing ambiguity); *see also Carr v. El Dorado Chem. Co.*, 1997 U.S. Dist. LEXIS, at 11 (Apr. 14, 1997) (declining to apply statutory privilege retroactively where audit “could not have been performed in reliance upon the fact that it would not be subject to discovery”).

<sup>37</sup> *Elec. Power Bd v. Woods*, 558 S.W.2d 821, 825 (Tenn. 1977).

resolved against the retrospective effect.”<sup>38</sup> Under the circumstances, the Court should hold that the PRP governs whether O’Neal can claim privilege as to pre-April 12, 2011 communications.

### **C. Application of Peer Review Privilege to O’Neal’s Pre-April 2011 Actions**

O’Neal has not satisfied any of the requirements to invoke the PRP as to his pre-April 2011 communications related to St. Thomas Neurosurgical.

First, he has not identified a putative “peer review committee” during the relevant time frame, let alone established that the committee meets the requirements set forth in Tenn. Code Ann. 63-6-§ 219(c). Absent the involvement of a peer review committee, O’Neal cannot invoke the privilege.

Second, even if O’Neal were to identify a qualifying peer review committee, it is almost inconceivable that he participated in “peer review proceedings,” namely “the evaluation and review of a physician’s professional conduct, competence, and ability to practice medicine.” O’Neal would need to demonstrate that an (as yet unidentified peer review committee) specifically asked him to provide information or services to aid that committee in evaluating and reviewing a particular physician’s professional conduct, competence, and ability to practice medicine. The duties set forth in the 2007 O’Neal Contract do not reference peer review or indicate that O’Neal’s services were designed for use in peer review of St. Thomas Neurosurgical’s physicians, rather than St. Thomas Neurosurgical’s business practices as a whole. Moreover, according to Ms. Schamberg, only she and Dr. Culclasure were responsible for making the decision to purchase compounded products from NECC. If that is true, then there is no reason to believe that St. Thomas Neurosurgical consulted Mr. O’Neal in the first place before making that decision, let alone on issues relating peer review of a particular physician at

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<sup>38</sup> *Henderson v. Ford*, 488 S.W.2d 720, 721 (Tenn. 1972).

the behest of a peer review committee. Mr. O’Neal cannot reasonably assert the PRP as a privilege against disclosing the fact that he was *not* consulted in the first place (by a peer review committee or otherwise).

As to the PSC’s document requests, Mr. O’Neal cannot reasonably claim that the PRP affords a blanket privilege against disclosing *any and all* pre-April 2011 records reflecting communications about compounding pharmacies, NECC, or Depo-Medrol and MPA (in generic form or otherwise). Mr. O’Neal would need to show why the PRP applies *to each communication withheld* – and it strains credulity to believe that he could do so in good faith as to all (or perhaps any) of the documents requested. For example, if Mr. O’Neal communicated with St. Thomas Neurosurgical in 2008 about compounding pharmacies, the communication would *not* be privileged unless he could show (1) that the communication was made by or at the behest of a peer review committee, and (2) assuming that to be the case, that the communication was intended to aid that committee in evaluating and reviewing *a particular physician’s professional conduct, competence, and ability to practice medicine*. As the Tennessee Supreme Court made clear in *Lee*, the mere fact that a clinic (St. Thomas Neurosurgical) may have consulted a third party (Mr. O’Neal) on clinic-related matters – even if those matters ultimately impact patient health – is insufficient to invoke the PRP as a basis for non-disclosure. Again, based on the terms of the 2007 O’Neal Contract, there is no reason to believe that any of Mr. O’Neal’s pre-April 2011 communications are privileged under the PRP.

Under the circumstances, O’Neal’s invocation of the PRP to protect against the disclosure of any substantive information (both records and testimony) related to his contractual relationship with St. Thomas Neurosurgical before April 12, 2011 is unsupportable. The PSC submits that O’Neal should be compelled (1) to make a complete document production; (2) to

provide complete testimony for time period before April 12, 2011; and (3) to the extent that he invokes the PRP for pre-April 12, 2011 communications, that he (a) assert that privilege at the deposition in response to a specific question, and (b) provide a privilege log that explains the basis for the privilege as to each document withheld, including the date of the communication, the identity of the peer review committee purportedly at issue, the basis for asserting that the communication related the committee's review of a particular physician's professional conduct, competence, and ability to practice medicine, and the identity of that particular physician.

## **II. The QICP (Applicable from April 12, 2011 Forward)**

### **A. The Quality Improvement Committee Privilege**

Effective April 12, 2011, Tennessee repealed the PRP statute and supplanted it with a new statute, Tenn. Code Ann. § 68-11-272. The new statute, which creates a privilege related to "Quality Improvement Committees" ("QICs") contains terms that are different from, and arguably broader than, those set forth in the PRP statute. The PSC has not located any case law authority concerning the QICP.

Under the newer statute, a privilege applies under certain circumstances to information related to a QIC, which is defined as a committee formed or retained by a healthcare organization that is designed (in whole or in part) to perform any of several enumerated functions.<sup>39</sup> The statute defines a healthcare organization broadly (*see* Tenn. Code Ann. § 68-11-272(b)(1)) and defines the "records" of a QIC to include to include "all documentation generated in connection with the activities of a QIC" (*Id.* at § 272(b)(5)). The statute provides

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<sup>39</sup> *Id.* at § 68-11-272 (current 2015). Those functions include, *inter alia*: (A) Evaluation and improvement of healthcare services rendered; . . . (E) reduction of morbidity or mortality; . . . (G) Research. . . (L) Evaluation, review or improvement of methods, procedures or treatment being utilized; . . . [and] (O) Activities to determine the healthcare organization's compliance with state or federal regulations."



that records of a QIC and testimony or statements relating to the activities of a QIC are confidential, privileged, and protected from direct or indirect means of discovery, subpoena, or admission into evidence (*id.* at § 272(c)(1)). The PSC will refer to the QIC privilege as the QICP.

**B. Application of the Quality Improvement Committee Privilege to O’Neal’s Post-April 12, 2011 Actions**

The Court must consider how the QICP applies to O’Neal’s activities under the 2007 O’Neal Contract (which was in effect at least through September 1, 2012) and under the Second O’Neal Contract (which went into effect as early as September 1, 2012).

Before performing that analysis, the Court should bear in mind that significant questions remain as to why the Second O’Neal Contract was not executed by O’Neal until *April 2013*, even though it purports to have been effective as of September 1, 2012. Regardless of whether O’Neal can invoke the QCIP as to his activities after April 12, 2011, the PSC should be permitted to question O’Neal about (and receive records concerning) the nature of Second O’Neal Contract and the circumstances of its formation. The timing of the Second O’Neal Contract is highly suspicious: Schamberg signed the document and dated it September 7, 2012, just *three weeks* before the fungal meningitis outbreak; O’Neal executed it over six months later, apparently while counsel for St. Thomas Neurosurgical was engaged in a discovery dispute concerning its relationship to O’Neal (and just before the plaintiff moved to compel), and the contract purported to be retroactive to the time frame just before the outbreak. The circumstances strongly suggest that St. Thomas Neurosurgical realized that O’Neal’s communications were *not* subject to the QCIP, at which point St. Thomas Neurosurgical created the new contract and backdated it in an effort to paper over this issue and to invoke the privilege

retroactively. Whether the PSC's suspicion is true will depend on information known to O'Neal and not subject to a claim of privilege.

At any rate, the QCIP, while arguably broader in scope than the PRP, is not limitless. To invoke the QCIP, O'Neal must – for the time period after April 12, 2011 – identify a QIC associated with St. Thomas Neurosurgical, show that he was acting at the behest of that QIC in generating information, and show that the specific information he seeks to shield from disclosure was related to the activities of the QIC. To date, O'Neal has done none of these things.

The PSC submits that O'Neal's duties under the 2007 O'Neal Contract do not support a blanket invocation of the privilege: the contract makes no reference to a QIC or that O'Neal was retained to assist a QIC. Thus, O'Neal cannot claim a blanket privilege under the QCIP statute for time frame from April 12, 2011 through at least September 1, 2012 (or later if the Second O'Neal Contract was not effective until April 2013).

As to the application of the QCIP to O'Neal's duties under the Second O'Neal Contract, the PSC concedes that the contract does reference a QIC. However, that this reference is alone is insufficient to demonstrate that the QCIP *per se* shields O'Neal from having to testify and produce records, because it enumerates just one potential duty among many. Also, the circumstances of the formation of that contract are questionable, raising the possibility that St. Thomas Neurosurgical added the reference specifically to paper over the fact that O'Neal's activities were *not* subject to the QCIP. Regardless, the burden is on O'Neal, not the PSC, to justify the assertion of the privilege.

One additional over-arching point as it relates to the QCIP: as with the PRP, it would be inappropriate for O'Neal to invoke the QCIP to refuse to testify that he was *not* consulted and

that he did *not* communicate on certain issues. In other words, if there were not “records” or “statements” made on a particular issue, there is no privileged information in the first place.

The PSC anticipates that O’Neal may seek to introduce additional affidavits and evidence to justify why he is invoking the QCIP as to post-April 2011 information. The introduction of more evidence on this issue would merely reinforce that, at a bare minimum, the PSC is entitled to discovery from O’Neal concerning facts related to his invocation of the QCIP: What duties did he perform at different points in time? To what QICs does he contend he reported to and when? What categories of information did he generate for those QICs? Was he actually consulted or did he generate information on specific topics, such as compounding pharmacies or the decision to purchase products from NECC? The PSC is at least entitled to probe those topics at deposition.

### **III. The Tennessee State Court Decision**

The PSC anticipates that O’Neal will contend that the decision of the Tennessee Circuit Court in *Reed* (attached as Exhibit 10 to the Gastel Declaration) requires that this Court deny the PSC’s motion. The Tennessee decision does not bind the court here for multiple reasons.

First, and most importantly, the Tennessee Circuit Court considered only whether the QCIP protected certain information from disclosure, not whether the PRP protected similar information for the pre-April 12-2011 time frame. It appears that the Tennessee Circuit Court simply assumed, incorrectly and without deciding, that the QCIP applied retroactively. Indeed, the defendants’ submissions concerning the privilege issue failed to acknowledge the differences between the two laws and collapsed the analysis into only a QCIP analysis. The defendants presented no justification for that assumption and the Tennessee court did not reference the issue, let alone address it. As the PSC has explained in this brief, state courts consistently hold that

changes to medical peer review privilege statutes do *not* apply retroactively to shield from disclosure information that was not privileged at the time it was created, and there is no reason to abrogate Tennessee's presumption that a new statute (here, the QCIP) applies only prospectively. The PSC is confident that if the Tennessee court had addressed this distinction relative to O'Neal's pre-April 12, 2011 activities, the court would have reached the same result, and the PSC submits that it was clear error for the Tennessee court to have assumed otherwise.

Second, the Tennessee Circuit Court was not asked to address some of the additional distinctions addressed by the PSC here, such as whether Mr. O'Neal can refuse to testify that he was *not* consulted or did *not* create any materials on a particular topic.

Third, even as to the QCIP analysis that it addressed, the Tennessee court's decision comprises only an abbreviated, non-binding, unpublished analysis on a matter of first impression. Accordingly, it is at most persuasive authority with respect to the application of the QCIP for O'Neal's post-April 12, 2011 activities, and the PSC believes that it was incorrect and therefore should be given little persuasive weight by this Court even as to the limited issue that it actually addressed.

### **CONCLUSION**

The Court should compel O'Neal (1) to testify and to produce complete records for the time frame prior to April 12, 2011 without objection, (2) to testify and to produce records that do not fall within the QCIP after April 12, 2011; and (3) to produce a detailed privilege log for any records withheld from production.

Date: November 24, 2015

Respectfully submitted:

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*Plaintiffs' Steering Committee*

**CERTIFICATE OF SERVICE**

I, Benjamin A. Gastel, hereby certify that I caused a copy of the foregoing *Plaintiffs' Steering Committee's Memorandum in Support of Motion to Compel Compliance with Subpoena to Michael O'Neal* to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: November 24, 2015

/s/ Benjamin A. Gastel

Benjamin A. Gastel